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Single-center experience using three different second generation devices for transcatheter aortic valve implantation

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Background: Transcatheter aortic valve implantation (TA-AVI) has become a well accepted alternative treatment for patients with severe aortic stenosis and high surgical risk. While first generation devices yield acceptable clinical and hemodynamic outcomes, second generation devices have become available, potentially facilitating implantation procedures and improving postoperative outcome.

Methods: From March 2008 through December 2012, a total of 420 patients were treated by TA-AVI at our center. Of these, 142 patients (80.3±6.1 years, 60% male, 19.3±9.8% logEuroSCORE I) received second generation devices for TA-AVI (TA-AVI2nd; JenaValve n=63, Symetis Acurate n=38, Medtronic Engager n=41). Data were prospectively entered into a dedicated database and retrospectively analyzed.

Results: In 142 patients after TA-AVI2nd, procedure time, fluoroscopy time and amount of contrast used were 92.2±49.1 min, 7.4±4.1 min and 168.3±82.4 ml respectively. Acute device success was achieved in 97.2% (138/142). 30-day mortality was 4.2% (6/142), periprocedural stroke rate was 1.4% (2/142). The degree of paravalvular leakage at discharge was 0.5±0.6 with PVL ≥ grade 2 in four patients only (2.8%). At discharge, transvalvular gradients were mean/max 10.8±4.1 / 21.4±7.6 mmHg respectively.

Conclusions: TA-AVI2nd using JenaValve, Symetis Acurate and Medtronic Engager devices yield excellent acute clinical and hemodynamic outcomes in this early single-center experience. Ease of implantability and good functional outcome with low rates of relevant PVL appear to be the most obvious improvements compared to first generation devices. TA-AVI2nd devices may eventually lead to a patient-centered tailor-made approach to transcatheter treatment of aortic stenosis in high-risk patients. Before recommendations on which device is best suited for which patient can be made, experience in larger patient numbers and with longer follow-up will have to be awaited.

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Transient and Permanent Cardiac Conduction Abnormalities Following Transcatheter Aortic Valve Implantation

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Background: In transcatheter aortic valve implantation (TAVI), conduction abnormalities (CA) may complicate the peri- and postoperative patient management and outcome. Herein, both atrio-ventricular and intra-ventricular CA occur, and trigger permanent pacemaker (PP) implantation in some patients. However, within the time course of postinterventional prosthetic healing, CA may in part be reversible.

Methods: Out of 121 patients that underwent TAVI, a total of 69 patients were identified with no baseline ventricular conduction disturbances or previous PP implantation (n=41 Medtronic CoreValve, n=28 Edwards Sapien TAVI prostheses). 12-lead electrocardiograms were recorded before TAVI, on day one and before hospital discharge, as well as one month and 6 months after the procedure.

Results: At day 1 following TAVI, new-onset left bundle branch block (LBBB) was observed in 36 (52%) and right bundle branch block (RBBB) in 2 (3%) of the patient collective, and 2 (3%) patients had undergone PP implantation directly after the TAVI procedure for complete atrioventricular block (AVB). Accordingly, mean QRS duration increased from 98.3 ± 10.8 ms to 140.2 ± 30.9 ms (p<0.0001) on day 1. New-onset LBB completely resolved during in-hospital stay in 4 (11%) of patients, and mean QRS duration decreased to 123.9 ± 28.7 ms at discharge, 109.0 ± 26.2 ms at 30 days, and 104.7 ± 10.9 ms at 6 months. New-onset atrial fibrillation (AF) was seen in 11 (16%) of patients. The mean PR interval in those patients without AF at baseline or 1d follow-up (n=48) increased from 191.0 ± 51.2 ms to 246.7 ± 96.3 ms (p=0.004). Thereafter, PR interval in those patients that were neither paced nor developed AF decreased to 210.6 ± 79.0 ms at hospital discharge, 206.2 ± 48.7 ms at 30 days and 205.3 ± 61.0 ms at 6 months. Since criteria for PP implantation after TAVI are not standardized, and the present patient cohort includes our center's initial TAVI patients, the rate of PP implantation was rather high, with 29/68 (43%) patients receiving a PP within 6 months following TAVI, of whom 27 (93%) underwent PP implantation during their TAVI hospital stay. Most frequent indications were complete AVB (46%) and new LBBB (38%).

Conclusions: Atrio-ventricular and intra-ventricular conduction disturbances frequently occur after TAVI. However, the observed prolongation in PR and QRS durations in patients that were not considered for PP implantation apparently resolve – at least in part – with time following the TAVI procedure.

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Transcatheter Aortic Valve Implantation In Patients With Severe Aortic Valve Stenosis and Large Aortic Annulus, Using the Self-Expanding 31-mm Medtronic CoreValve Prosthesis: First Clinical Experience

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Background: With the introduction of the Medtronic CoreValve 31mm prosthesis (Medtronic Inc., Minneapolis, MN, USA) patients with large aortic annulus have become eligible for transcatheter aortic valve implantation (TAVI). So far, no studies regarding the clinical experiences with this prosthesis have been published. The aim of this study is to evaluate the feasibility, efficacy and safety of TAVI using the Medtronic CoreValve 31mm prosthesis in patients with severe aortic valve stenosis and large aortic annulus.

Methods: Five institutions in the Netherlands and Italy participated in a retrospective multi-center registry. Clinical, procedural and imaging data of patients treated with the CoreValve 31mm were retrospectively collected in accordance with the VARC-2 criteria.

Results: Between August 2011 and November 2012, 47 patients (44 males, mean age 77.6 ± 8.9 years) received the CoreValve 31mm prosthesis for severe aortic stenosis. Device success (no all-cause 30-day mortality and correct positioning of a single valve with intended performance) was achieved in 31 patients (66.0%). Reasons for not fulfilling the device success criteria were: in-hospital mortality in 2 patients (4.2%), significant prosthetic aortic regurgitation in 4 patients (8.5%) and second valve implantation in 10 patients (21.3%) (8 cases of malpositioning with high-grade aortic regurgitation, 1 acute and 1 delayed valve dislocation). Peak and mean transaortic gradients decreased significantly (p < 0.001). The rate of pacemaker implantations was 31.9%.

Conclusions: In this retrospective multi-center registry, transcatheter treatment of severe aortic valve stenosis with the Medtronic CoreValve 31mm device appeared to be challenging, even in experienced hands. If the prosthesis is properly implanted, it offers adequate valve hemodynamics and proper functioning.

TCT-785

The “Eyeball Test” in Aortic Stenosis: Characterizing Subjective Frailty with Objective Measures

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Background: Assessment of frailty complements traditional risk assessment in high-risk older adults with aortic stenosis (AS). Subjective frailty assessment is widely used, but its associations with objective markers of frailty are poorly characterized.

Methods: Frailty was subjectively assessed by an interventional cardiologist or physician assistant in high risk older adults with AS in the valve clinic at our center. A trained coordinator then objectively assessed frailty by measuring 15 foot walk time, grip strength, independence in activities of daily living (ADL), and collecting serum albumin as a marker of malnutrition. Markers of frailty were compared between those considered frail and not frail by the subjective assessment.

Results: Among 92 patients, 28 (30%) were considered frail by subjective assessment. Those considered frail were older (86±6 vs 84±6 yrs, p=0.06) with higher STS scores (9.8±4.4 vs 7.2±3.0, p=0.009), but did not differ in gender (64% vs 50% female, p=0.2), or BMI (25.6±7.3 vs 25.5±4.2, p=0.97). The frail group had more ADL dependence (79 vs 36%, p=0.0002), slower gait speed (0.37±0.16 vs 0.67±0.17 m/s, p<0.0001), lower grip strength (women: 12.6±4.9 vs 16.3±4.9 kg, p=0.01, men: 18.0±7.9 vs 26.5 kg, p=0.01), and lower albumin (3.6±0.48 vs 4.0±0.48 g/dL, p<0.0001).

Conclusions: Among older adults with AS evaluated in a specialized valve center, those considered frail by subjective assessment were slower, weaker, more malnourished, and had more ADL impairment. Future studies will be needed to determine the optimal frailty assessment to predict outcomes in older adults with AS.

